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PATENT
Customer No. 22,852
Attorney Docket No. 08203.0014

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Franciscus Laurens MOLL et al.	)	
	)	
Application No.: 09/910,008	)	Group Art Unit: 3738
	)	
Filed: July 23, 2001	)	Examiner: Unknown
	)	
For: REMOVABLE STENT	)	

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

CLAIM FOR PRIORITY

Under the provisions of Section 119 of 35 U.S.C., Applicants hereby claim the benefit of the filing date of Ireland Patent Application Number 2001/0114, filed February 13, 2001; Ireland Patent Application Number 2000/0592, filed July 21, 2000; Netherlands Patent Application Number 1011232, filed February 5, 1999; and Netherlands Patent Application Number 1011903, filed April 27, 1999, for the above-identified United States Patent Application.

In support of Applicants' claim for priority, certified copies of the priority applications are filed herewith.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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Dated: November 13, 2001

By: _____
Roland G. McAndrews, Jr.
Reg. No. 41,450

230772_1

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Translation

K I N G D O M O F T H E N E T H E R L A N D S

INTELLECTUAL PROPERTY OFFICE

It is declared hereby that a patent application was filed in the Netherlands on February 5, 1999 under No. 1 011 232, in the name of Surgical Innovations v.o.f. in Elspeet for an invention entitled: "Removable stent",
and that the documents affixed hereunto fully correspond to the documents originally filed.

Declared in Rijswijk, on August 8, 2001.
The managing director of the Intellectual Property Office, for him

Mrs. M.M.Enhus

KONINKRIJK DER NEDERLANDEN

Bureau voor de Industriële Eigendom

Hierbij wordt verklaard, dat in Nederland op 5 februari 1999 onder nummer, 1011232

ten name van:

SURGICAL INNOVATIONS V.O.F.

te Elspeet

een aanvrage om octrooi werd ingediend voor:

"Verwijderbare stent",

en dat de hieraan gehechte stukken overeenstemmen met de oorspronkelijk ingediende stukken.

Rijswijk, 8 augustus 2001

De Directeur van het Bureau voor de Industriële Eigendom,
voor deze,

mw. M.M. Enhus

ABSTRACT

Device for internally supporting body vessels, such as blood vessels, the urinary tract, the digestive tract, and airways, said device comprising:

- an outer wall, and
- an inner wall, whereby both the inner and outer wall are expandable and contractible between an expanded support position, in which support position the outer wall contacts an internal surface of the body vessel, and a contracted displacing position wherein the device is displaceable to and from a pre-desired location in the body vessel, and,
- releasable locking means for releasibly locking the device in the expanded support position and/or the contracted displacing position.

7 II

REMOVABLE STENT

The present invention relates to a device for internally supporting body vessels, an assembly comprising said device and means for introducing and/or removing said device from the vessel, to a process for arranging the device within a vessel and to the use of said device and assembly.

A serious medical problem is the silting up of blood vessels, for instance with calcium, this being called arteriosclerosis. This can lead to a blockage of the blood vessel, called stenosis.

Stenosis of blood vessels can cause a complete blockage of the blood vessel which leads to serious health consequences, for example circulatory problems, for the sufferer, whereby a rapid deterioration in health ensues. Advanced stenosis if not operated upon can cause wastage and death of body tissue necessitating in certain cases, in amputation.

Inflatable, tubular prostheses are known, which can be inserted into blocked tubular organs and subsequently expanded in order to re-open these organs.

Further since such tubular prostheses, commonly referred to as stents, are made from material alien to the body, it is often necessary to remove the stent once the acute situation has been treated. Otherwise there exists a very real danger of thromboses and infections resulting from bodily rejection of the stent material.

Such prostheses, or stents, are currently surgically removed, often during a complicated operation carried out under narcosis. If this however presents difficulties or possible dangerous consequences to the patient, the stents are allowed to remain within the patient lead to the above consequences.

According to a first aspect of the present invention, there is provided a device according to any of the claims 1-10.

The device according to the present invention can therefore be arranged between an expanded, locked, arrangement wherein the body vessel is treated, and can be released from this expanded, locked, arrangement into a contracted arrangement wherein the device may be displaced into the vessel or removed therefrom simply by guiding it through the body vessel concerned.

The stent may be provided with a medical tracer and/or radioactively 'loaded' in order to provide accurate medical diagnosis, i.e. by means of imaging, and/or very accurate, localized radiation therapy.

According to a second aspect of the present invention there is provided an assembly according to claims 11 or 12.

By means of such an expandable/deflateable balloon catheter for example, the device can be easily arranged between its expanded, treating arrangement and its contracted, displacing arrangement.

According to a third aspect of the current invention there is provided a process according to claims 13 or 14.

Such a process for introducing the above device, arranging the device in its expanded treating arrangement, and once the treatment period has expired, re-arranging the device in its contracted displacing position, whereby the device can be brought into and removed from the body vessel along the same route provides an extremely effective, easy method for treating body vessels, whereby the stent can be safely, efficiently and quickly inserted into/ removed from the body vessel.

According to further aspects of the present invention there is provided a method according to claim 15, and the uses according to claims 16-20.

The invention will now be further clarified by way of the following description which refer to the figures wherein:

- figure 1 shows a partially cut away perspective view of the arranging/removal of the device according to the present invention;
- figure 2 shows a perspective partially cut away view of the device within a blood vessel in its contracted arrangement around a deflated balloon catheter;
- figure 3 shows the arrangement in figure 2 whereby the device occupies its expanded, treating arrangement;
- figure 4 shows a perspective view of a first preferred embodiment of the device in a contracted arrangement;
- figure 5 shows the embodiment in figure 4 occupying its expanded, locked treating arrangement;
- figure 6 shows a further perspective view of the device in figures 4 and 5;
- figure 7 shows a partially cut away perspective view of the releasable locking means;
- figure 8 shows the locking means as in figure 7 when releasibly locked in the position;
- figure 9 shows a perspective view of a second preferred embodiment of the device according to the present invention;
- figure 10 shows a perspective view of a third preferred embodiment of the current invention; and
- figure 11 shows a fourth preferred embodiment of the device according to the present invention.

An assembly 1, according to the present invention, figures 1,2 and 3, has a guide wire 2 a catheter tube 4, expandable/contractible balloon catheter 6 and a stent 10 arranged around the balloon catheter 6.

The balloon catheter 6 can be inflated/deflated by means of the pipes 12 in connection with the catheter tube 4.

The stent 10 consists of four ring like elements 14 each ring provided with a first terminal part 16 and a second terminal part 18 at the other end thereof.

The rings 14 are formed from a single length of pre-tensioned material, for example surgical metal, whereby the terminal parts slide over one another when transforming between the expanded/contracted arrangements. When not being used, the device is so pretensioned, rather like a spring, that in this 'rest' state it occupies the contracted state, figure 4.

Each ring section 14 has an outer wall 20, which outer wall 20 contacts the internal surface of the body vessel when in its expanded treating position, and an inner wall 22 which contacts the balloon catheter 6, when the device is arranged thereon, figures 2,3.

The four rings 14 are joined to provide the tubular form of the device, by means of links 24.

The first terminal part 16, of each ring 14, see particularly figures 7 and 8 is provided with two laterally arranged down turned guiding lip-sections 26, and arranged there between with a down turned, somewhat truncated, releasable locking edge 28.

The second terminal part 18 of the rings 14 is provided with a number of laterally arranged receiving openings 30 which correspond with the locking edge 28, of terminal 16.

In a second preferred embodiment of the stent figure 9, the rings are joined by links arranged on the first terminal part of the rings, and the first terminal part is provided with a cut-away receiving section 40 which is releasably interlockable with a finger element 42 arranged on the second terminal part of the rings.

In a third preferred embodiment of the stent, figure 10, the first terminal parts of the rings are provided with depending studs 50 which are interlockable with corresponding U profiles 52 arranged on the second terminal parts of the rings.

In a fourth preferred embodiment of the stent as shown in figure 11, the first terminal ends of the rings are laterally provided with up turned cuffs 60 which co-operate with narrowing profiles 62 of the second terminal parts of the ring sections.

In use, the stent is arranged in its contracted state, see figures 2 and 4 around the deflated balloon catheter 6. The assembly is than guided into position to the pre-determined treatment site within a body vessel, as shown in figure 1, at which treatment site the balloon catheter is expanded. On inflation of the balloon catheter 6, the stent is unravelled so that the outer wall 20 thereof is pushed against the inner surface of the body vessel, see figure 3. The balloon catheter 6 is expanded to such an extent that terminal parts 16, respectively 18 of the rings are displaced, whereby the rings 14 are expanded, so that the second terminal part 18 of the rings 14, in the contracted state residing on the outer wall 20 of the rings 14, slips below the first terminal part 16 of the rings so that the locking edge 28 falls into one of the corresponding openings 30 and whereby the terminal part 18 is also stabilized by the depending lips 26, figure 8. In this position the stent is its expanded, treatment position.

The degree of expansion of the stent can be controlled by the degree of expansion of the balloon catheter. Body vessels of varying internal diameters are catered for by the presence of a plurality of receiving openings 30.

It will be clear that the embodiments as shown in figures 9,10 and 11 are expandable and lockable by the same principle.

Once the period of treatment has expired, the balloon catheter can once more be inserted into the body vessel and inflated to force open the stent whereby the locking means are decoupled, i.e. whereby the locking edge 28 is forced up out of the corresponding opening 30 whereby the two terminal parts of the rings are forced

further apart until the terminal part 16 slips again beneath the terminal part 18 to re-assume its pre-tensioned state, whereby the rings contract to once more grip around the balloon catheter. The balloon catheter can than be deflated whereby the two ends of the rings slide over one another until the stent re-assumes its pre-tensioned contracted position.

It will be obvious that the embodiments as shown in figures 9, 10 and 11 work by exactly the same principle.

The present invention is not limited to the above described preferred embodiments; the rights of the present invention are to be determined by the following claims, in which many modification are possible.

CLAIMS

1. Device for internally supporting body vessels, such as blood vessels, the urinary tract, the digestive tract, and airways, said device comprising:

- an outer wall, and
- an inner wall, whereby both the inner and outer wall are expandable and contractible between an expanded support position, in which support position the outer wall contacts an internal surface of the body vessel, and a contracted displacing position wherein the device is displaceable to and from a pre-desired location in the body vessel, and,
- releasable locking means for releasibly locking the device in the expanded support position and/or the contracted displacing position.

2. Device according to claim 1, wherein the outer and inner walls are provided in the form of one or more ring like elements.

3. Device according to claims 1 or 2, wherein the inner and outer walls comprise a first terminal part and a second terminal part.

4. Device according to claims 2 or 3 wherein the ring elements are interconnected by one or more linking members.

5. Device according to claim 4 wherein the releasible locking means comprise interlocking means provided on the first and/or second terminal parts.

6. Device according to claim 5 wherein the interlocking means comprise a catching element arranged on the first terminal part, said catching element being co-operable with a locking opening arranged on the second terminal part.

7. Device according to claim 6 further comprising guiding means for guiding the first terminal

part over the second terminal part during expansion and/ or contraction of the device.

8. Device according to claim 7 wherein the guiding means comprise one or more lip-sections in association with the first terminal part, which lip-suctions cooperate with the second terminal part.

9. Device according to any of the preceding claims further provided with a tracing agent, whereby the device is traceable when arranged in position within the body by means of medical locating techniques such as magnetic resonance imaging.

10. Device according to any of the claims 1-9 further provided with a radio-active material in order to provide localized radiation therapy.

11. Assembly for treating body vessel disorders, said assembly comprising a device according to any of the preceding claims, and,

- introducing and/or removing means for introducing and or removing the device to and/or from the desired location within a body vessel.

12. Assembly according to claim 11 wherein the introducing and or removal means comprise an expandable/deflateable balloon catheter.

13. Process for arranging a device according to any of the claims 1-10 within a body vessel, comprising the steps of,

- arranging the device in its contracted form around a balloon catheter,

- bringing the balloon catheter plus contracted device to a pre-determined position within a body vessel,

- expanding the balloon catheter whereby the device is also expanded, to such an extent that the releasably locking means are locked in position, whereby in this expanded use position the balloon catheter may optionally be deflated and removed.

14. Process according to claim 13 further comprising the steps of

- reintroducing a balloon catheter into the body vessel,

- expanding the balloon catheter against the inner wall of the device to such an extent that the device further is expanded in order to release the releasable locking means,

- followed by deflating the balloon whereby the device re-assumes its contracted position to grip around the balloon catheter,

whereafter the balloon catheter and device may optionally be removed from the body vessel.

15. Method for treating body vessels, utilizing a device according to any of the claims 1-10 and or the assembly according to the claims 11-12.

16. Use of a device according to any of the claims 1-10 and or the assembly according to claims 11-12 for treating the organs of the digestive tract.

17. Use of the device according to any of the claims 1 to 10 and/or the assembly according to claims 11 or 12 for treating vessels of the urinary tract.

18. Use of the device according to any of the claims 1 to 10 and or the assembly according to claims 11 or 12 for treating the vessels of the airways, such as the trachaea and bronchii, in particular in brachy therapy.

19. Use of the device according to any of the claims 1 to 10 and or the assembly according to claims 11 or 12 for treating blood vessels such as arteries and/or veins.

20. Use of the device according to any of the claims 1 to 10 and or the assembly according to claims 11 or 12 for locally radio-actively treating a body vessel.

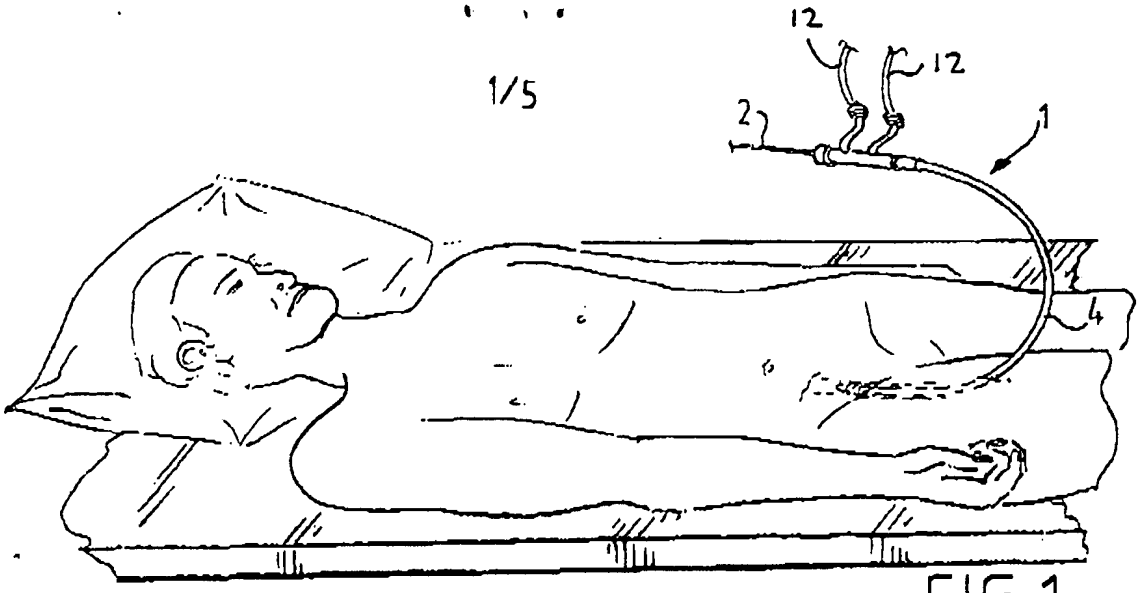

FIG.1

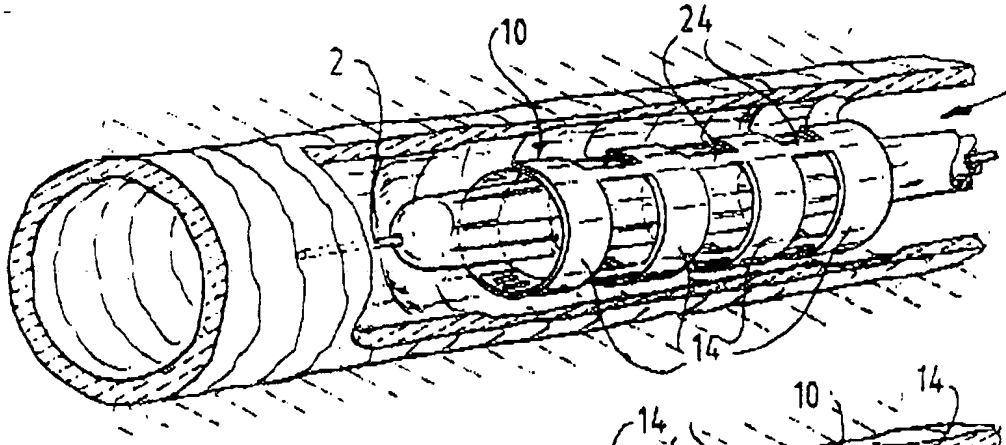

FIG.2

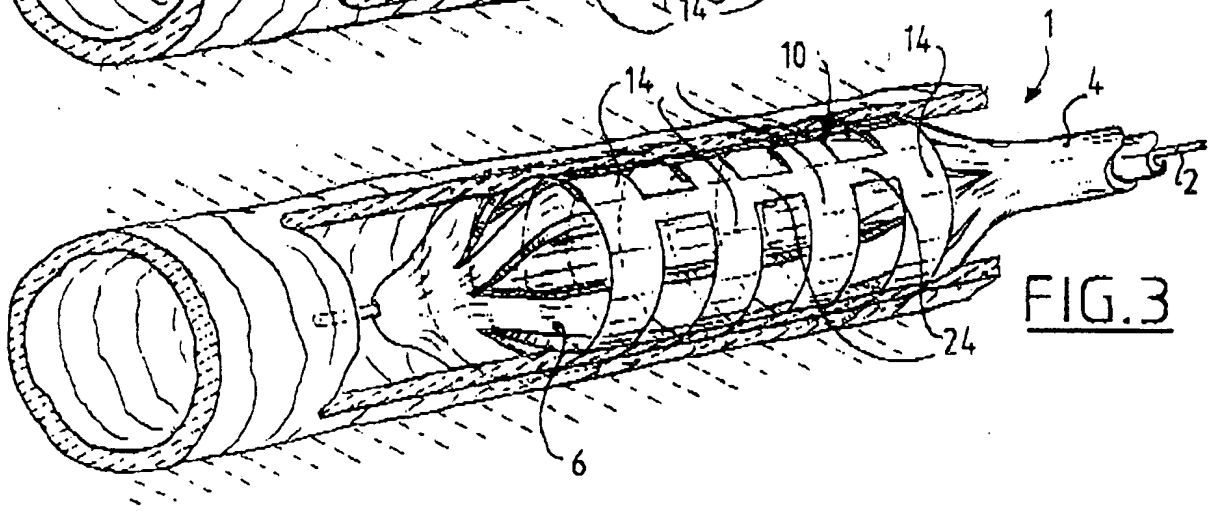

FIG.3

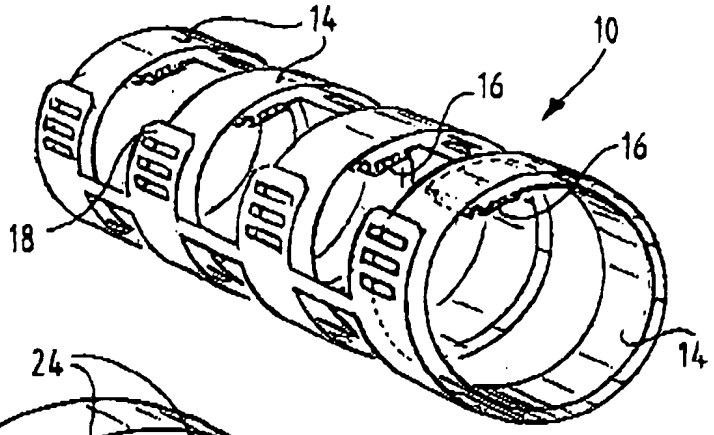

FIG.4

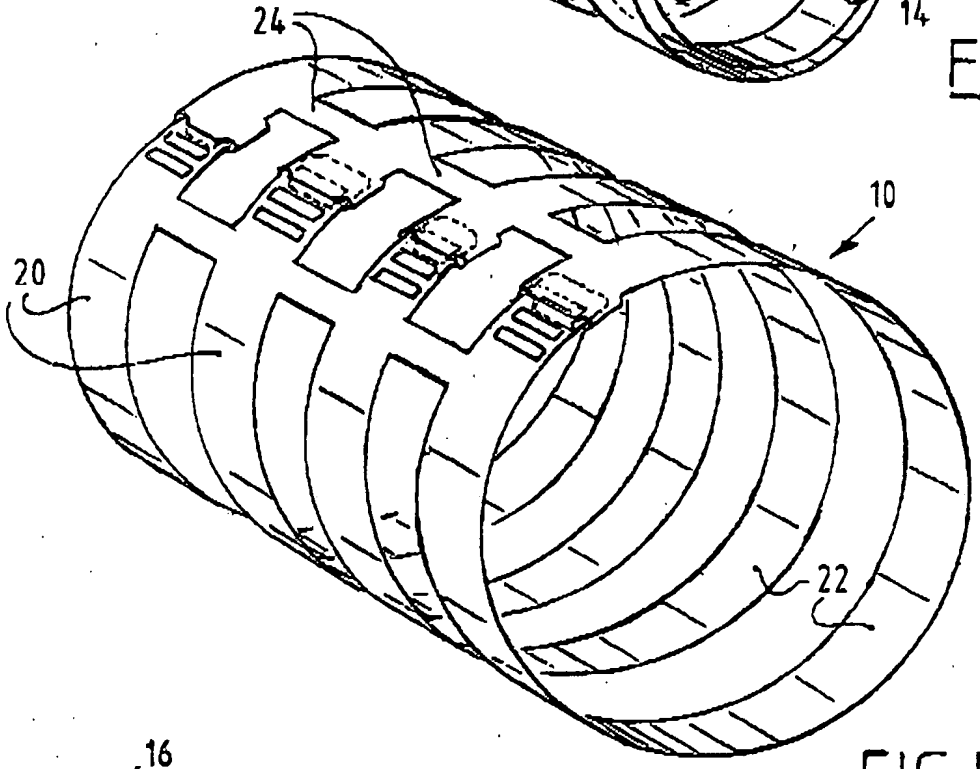

FIG.5

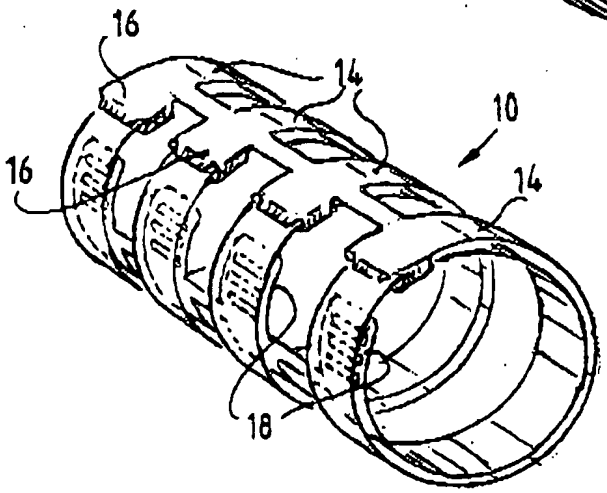

FIG.6

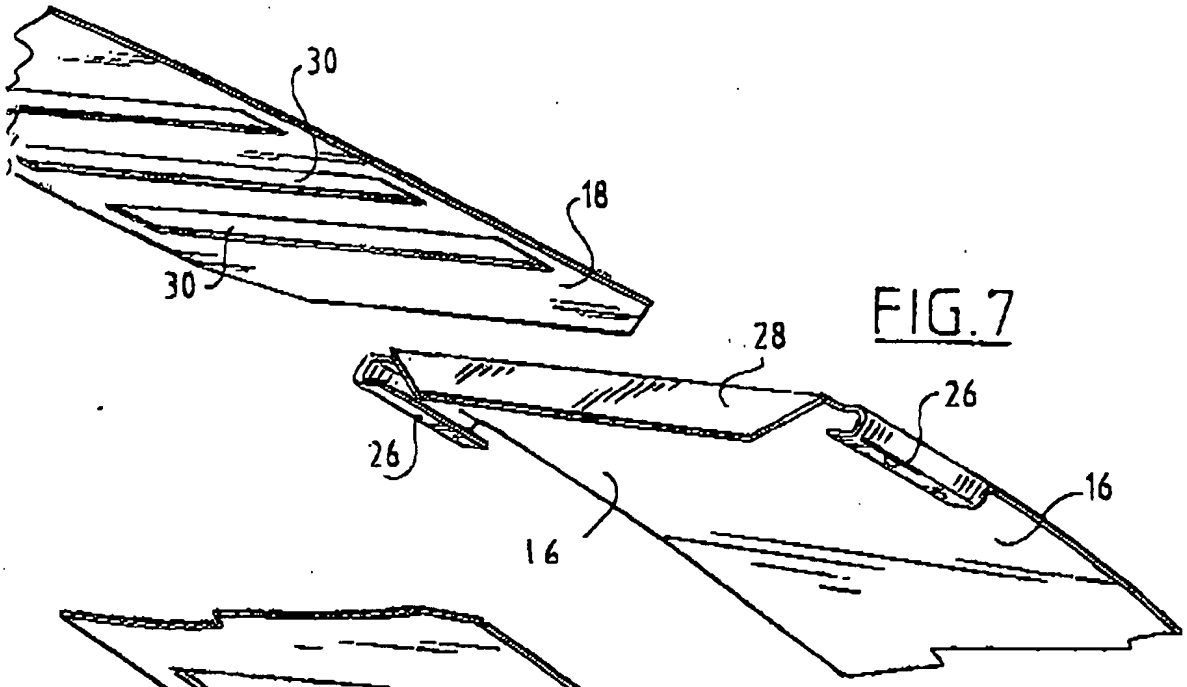

FIG.7

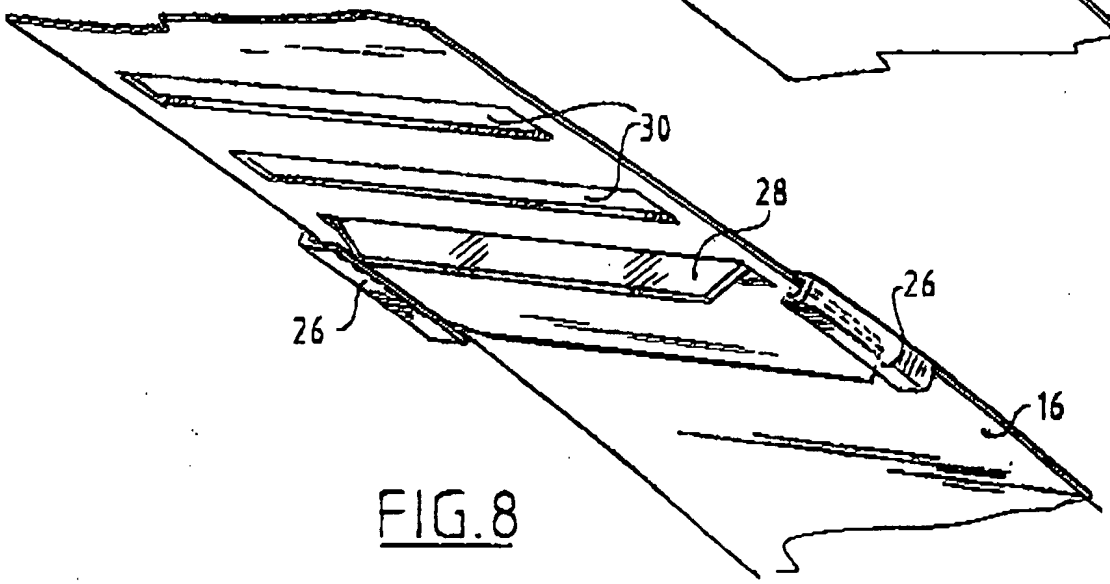

FIG.8

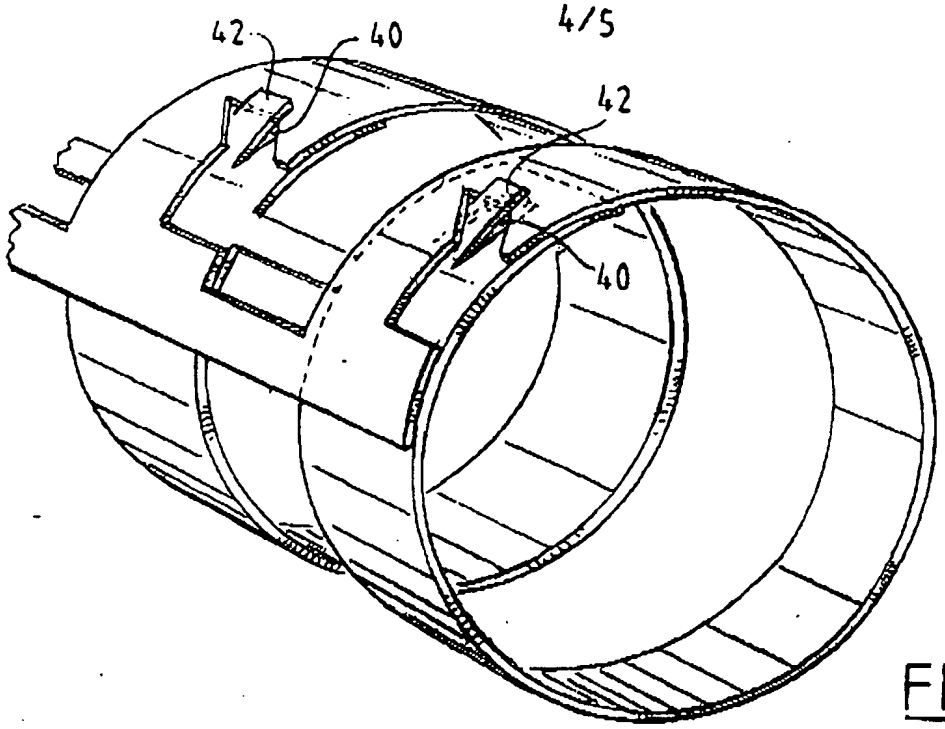

FIG.9

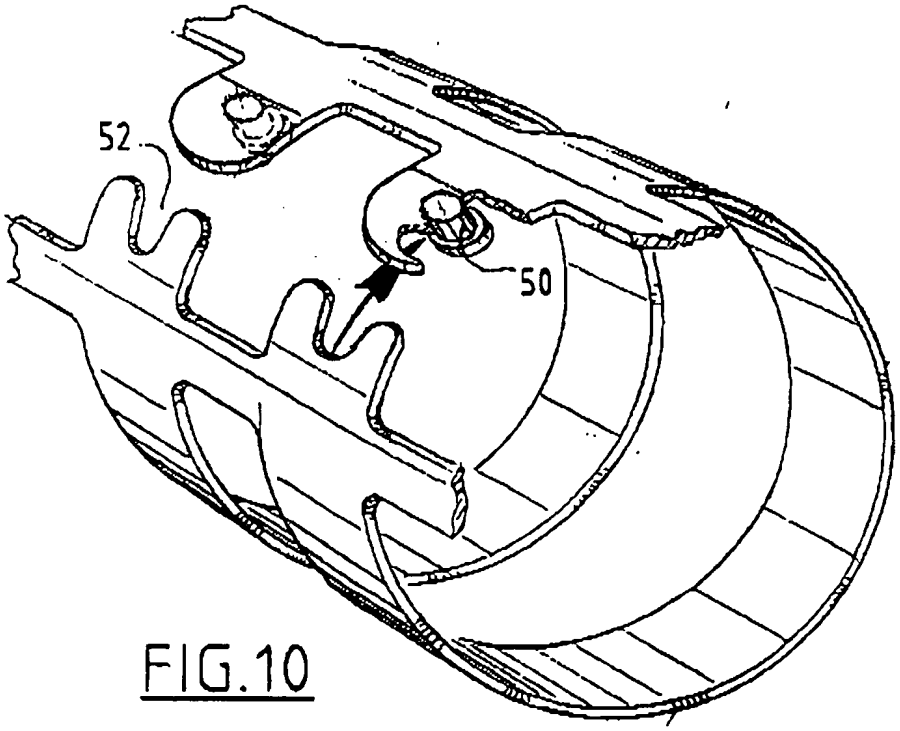

FIG.10

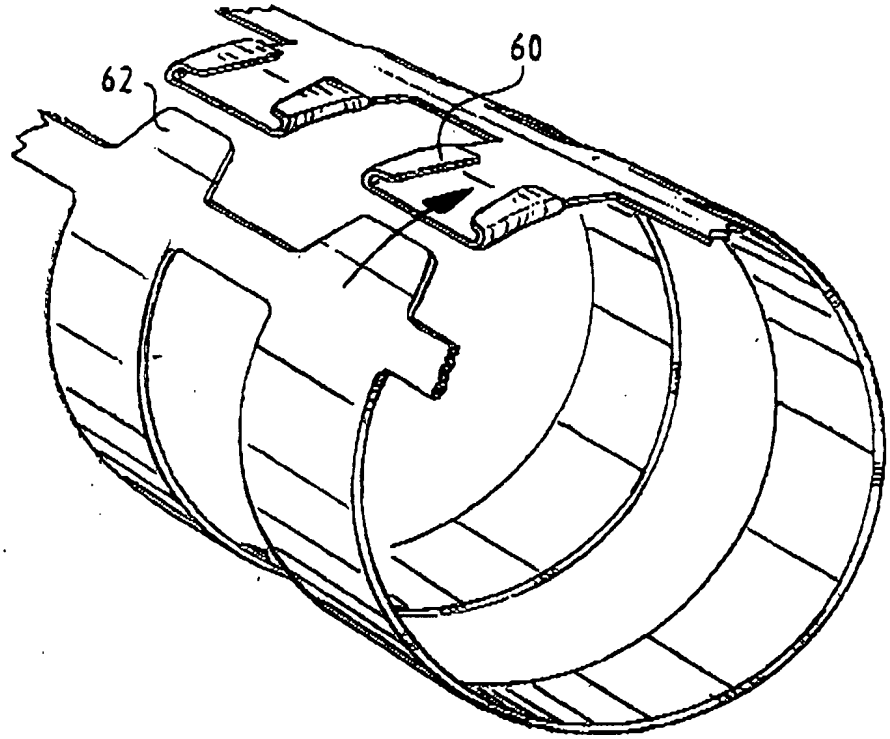

FIG.11